

(6) Gonad shielding of not less than 0.50 millimeter lead equivalent shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

(7) Individuals shall not be exposed to the useful beam unless (1) the radiation exposure occurs in the context of a previously established professional relationship between a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner pursuant to Iowa Code chapter 152 and a patient, which includes a physical examination by the practitioner of the patient unless such examination is not clinically indicated; and (2) such practitioner issues a written order for the radiation exposure. The written order shall be issued prior to the exposure unless the exposure results from care provided in an emergency or surgery setting. A verbal order may be issued provided the licensed practitioner is supervising the procedure and the order is documented in the patient's record after the procedure is completed. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and
2. Exposure of an individual for the purpose of healing arts screening except as authorized by 41.1(3)"a"(11).

(8) When a patient or film must be provided with auxiliary support during a radiation exposure:

1. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by 41.1(3)"a"(4), shall list individual projections where holding devices cannot be utilized;

2. Written safety procedures, as required by 41.1(3)"a"(4), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

3. The human holder shall be instructed in personal radiation safety and protected as required by 41.1(3)"a"(5)"2";

4. No individual shall be used routinely to hold film or patients; and

5. In those cases where the human patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

6. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

(9) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

1. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

2. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

3. Portable or mobile X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.

4. X-ray systems subject to 41.1(6) shall not be utilized in procedures where the source to human patient distance is less than 30 centimeters.

5. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

- Be positioned properly, i.e., tube side facing the correct direction, and the grid centered to the central ray;
- If the grid is of the focused type, be at the proper focal distance for the SIDs being used.

(10) All individuals who are associated with the operation of an X-ray system are subject to the requirements of 641—subrule 40.36(3) and rules 641—40.15(136C) and 641—40.37(136C). In addition:

1. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, it (they) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57.

2. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

(11) Healing arts screening. Any person proposing to conduct a healing arts screening program shall not initiate such a program in the state of Iowa without prior written approval of the agency. When requesting such approval, that person shall submit the information outlined in Appendix C of this chapter. The agency shall not approve a healing arts screening program unless the applicant submits data supporting the efficacy of the screening test in diagnosing the disease or condition being screened. If any information submitted to the agency becomes invalid or outdated, the applicant shall notify the agency in writing within five calendar days.

(12) Rescinded IAB 3/31/04, effective 5/5/04.

b. Information and maintenance record and associated information. Records in 41.1(3)“*b*”(1) and (3) below shall be maintained until the X-ray system is removed from the facility. There shall be two cycles of records on file for items in 41.1(3)“*b*”(2) below. The registrant shall maintain the following information for each X-ray system for inspection by the agency:

(1) User’s manual for the X-ray system;

(2) Records of surveys, calibrations, maintenance, and modifications performed on the X-ray system(s) with the names of persons who performed such services;

(3) A copy of all correspondence with this agency regarding that X-ray system.

c. X-ray utilization log. Except for veterinary facilities, each facility shall maintain an X-ray log containing the patient’s name, the type of examinations, the dates the examinations were performed, the name of the individual performing the X-ray procedure, and the number of exposures and retakes involved. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded. These records shall be kept until the facility is inspected by this agency or until all films listed on the utilization log have been purged.

d. Plan review.

(1) Prior to construction of all new installations, or modifications of existing installations, or installation of equipment into existing facilities utilizing X-rays for diagnostic or therapeutic purposes, the floor plans and equipment arrangements shall be submitted to the agency for review and verification that national standards have been met. The required information is denoted in Appendices A and B of this chapter.

(2) The agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

(3) The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 40.

e. Federal performance standards. All X-ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 to 1020.40 which were in effect at the time the unit was manufactured. All equipment manufactured before the effective date of 21 CFR 1020.30 to 1020.40 shall meet the requirements of the Iowa rules. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

f. X-ray film processing facilities and practices (except for mammography). Each installation using a radiographic X-ray system and using analog image receptors (e.g., radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

(1) Manually developed film.

1. Processing tanks shall be constructed of mechanically rigid, corrosion-resistant material; and

2. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer. The specified developer temperature and immersion time shall be posted in the darkroom. Deviations from the manufacturer's recommendations shall be in writing and on file at the facility. Documentation shall include justification for the deviation.

3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(2) Automatic processors and other closed processing systems.

1. Film shall be processed in accordance with the time-temperature relationships recommended by the film developer manufacturer.

2. Processing deviations from the requirements of 41.1(3) "f" shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing and special rapid chemistry).

3. All processing equipment shall be in good mechanical working order.

(3) Other requirements.

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to X-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in density greater than 0.1 when exposed out of the cassette in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best ensure radiographs of good diagnostic quality.

6. Outdated X-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

(4) Records shall be maintained to verify that the items in 41.1(3) "f" are performed according to the requirements. Records may be discarded only after an agency inspection has been completed and the facility determined to be in compliance.

g. Retention of films. Record retention of films shall be seven years for patients 18 years of age or older and seven years plus the difference between the patient's age and 18 for minors.

(1) If the facility is currently utilizing hard-copy film to store images, it may continue to use this method throughout the retention period.

(2) If the facility is currently utilizing computer media and also storing images in a hard-copy format, it may continue to use this method of retention throughout the retention period. If the images are also on computer media, the data should be backed up, or refreshed, at appropriate intervals as defined by the facility.

(3) If the facility is solely utilizing computer media to store study information for which a report is generated, the recording media is to be stored in conditions that will ensure that deterioration will not occur for the period required by this policy. The facility must maintain either retrieval or access or both to the stored images.

(4) If a patient's medical images are identified as being involved in a legal case, the records should immediately be coded appropriately, and maintained for the required time frame defined in this paragraph. At the time the records have reached the end of the appropriate time frame for retention, the previously identified responsible individuals involved in the legal action should be contacted for further instruction.

(5) If records are temporarily transferred to any party, appropriate information relating to location, date of release, and individual having custody of the records should be maintained.

(6) A facility that is ceasing operations must either transfer its film records to another facility or provide the film records to its patients. A certified letter as to the location, or disposition, of the film records must be sent to notify the patients of the transferal.

41.1(4) General requirements for all diagnostic X-ray systems. In addition to other requirements of this chapter, all diagnostic X-ray systems shall meet the following requirements:

a. Warning label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This X-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

b. Battery charge indicator. On battery-powered X-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

c. Leakage radiation from the diagnostic source assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens ($25.8 \mu\text{C/kg}$) in one hour when the X-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

d. Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens ($0.516 \mu\text{C/kg}$) in one hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled X-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

- e. Beam quality.
- (1) Half-value layer.

1. The half-value layer of the useful beam for a given X-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an X-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I

Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

2. and 3. Rescinded IAB 4/8/98, effective 7/1/98.

4. For capacitor energy storage equipment, compliance with the requirements of 41.1(4)“e” shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

5. The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

(2) Filtration controls. For X-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by 41.1(4)“e”(1)“1” is in the useful beam for the given kVp which has been selected.

f. Multiple tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the X-ray control panel and at or near the tube housing assembly which has been selected.

g. Mechanical support of tube head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the X-ray system.

h. Technique indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of 41.1(4) "h"(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(3) The technique indicators shall be accurate to within manufacturer's standards.

i. Rescinded IAB 3/30/05, effective 5/4/05.

41.1(5) *Fluoroscopic X-ray systems except for computed tomography X-ray systems.* All fluoroscopic X-ray systems shall be image intensified and meet the following requirements:

a. Limitation of useful beam.

(1) Primary barrier.

1. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

2. The X-ray tube used for fluoroscopy shall not produce X-rays unless the barrier is in position to intercept the entire useful beam.

(2) Fluoroscopic beam limitation.

1. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the X-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

2. For uncertified fluoroscopic systems with a spot film device, the X-ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than 20 centimeters from the tabletop to the film plane distance.

3. For uncertified fluoroscopic systems without a spot film device, the requirements of 41.1(5) "a"(2)"1" apply.

4. Other requirements for fluoroscopic beam limitation:

- Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the X-ray field;

- All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with stepless adjustment of the X-ray field or with means to further limit the X-ray field size at the plane of the image receptor to 125 square centimeters or less;

- If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of 5 centimeters by 5 centimeters or less;

- For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor;

- For noncircular X-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the X-ray field which pass through the center of the visible area of the image receptor.

(3) Spot-film beam limitation. Spot-film devices shall meet the following requirements:

1. Means shall be provided between the source and the patient for adjustment of the X-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the X-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the X-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

2. Neither the length nor the width of the X-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID;

3. It shall be possible to adjust the X-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, 5 centimeters by 5 centimeters;

4. The center of the X-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID; and

5. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(4) Override. If a means exists to override any of the automatic X-ray field size adjustments required in 41.1(5) "a"(2) and 41.1(5) "a"(3), that means:

1. Shall be designed for use only in the event of system failure;

2. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

3. Shall have a clear and durable label as follows:

FOR X-RAY FIELD LIMITATION SYSTEM FAILURE

b. Activation of the fluoroscopic tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the X-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

c. Exposure rate limits.

(1) Entrance exposure rate allowable limits.

1. Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or

- When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

2. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

3. Compliance with the requirements of 41.1(5)“c” shall be determined as follows:

- If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle;
- If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;
- All C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.
- For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the X-ray table and in the direction of the X-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral X-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the X-ray table.

4. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 10 roentgens (2.6 mC/kg) per minute in either mode at the point where the center of the useful beam enters the patient, except:

- During recording of fluoroscopic images; or
- When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

5. Any fluoroscopic equipment manufactured after May 19, 1995, which can exceed 5 roentgens (1.3 mC/kg) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 10 roentgens (2.6 mC/kg) per minute with an upper limit of 20 roentgens (5.2 mC/kg) per minute when the high level control is activated.

6. Conditions of periodic measurement of maximum entrance exposure rate are as follows:
- The measurement shall be made under the conditions that satisfy the requirements of 41.1(5)“c”(1)“3”;
 - The kVp, mA, or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;
 - The X-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce either a milliamperage or kilovoltage or both to satisfy the conditions of 41.1(5)“c”(1)“3.”
- (2) Reserved.
- d. Barrier transmitted radiation rate limits.
- (1) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens (0.516 $\mu\text{C/kg}$) per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.
- (2) Measuring compliance of barrier transmission.
1. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.
2. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.
3. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.
4. Movable grids and compression devices shall be removed from the useful beam during the measurement.
- e. Indication of potential and current. During fluoroscopy and cinefluorography the kV and the mA shall be continuously indicated.
- f. Source-to-skin distance. The SSD shall not be less than:
- (1) 38 centimeters on stationary fluoroscopes installed on or after August 1, 1974,
 - (2) 35.5 centimeters on stationary fluoroscopes which were in operation prior to August 1, 1974,
 - (3) 30 centimeters on all mobile fluoroscopes, and
 - (4) 20 centimeters for mobile fluoroscopes used for specific surgical application.
- (5) The written safety procedures must provide precautionary measures to be adhered to during the use of this device in addition to the procedures provided in 41.1(3)“a”(4).
- g. Fluoroscopic timer.
- (1) Means shall be provided to preset the cumulative on-time of the fluoroscopic X-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.
- (2) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset.
- h. Control of scattered radiation.
- (1) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

(2) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

1. Is at least 120 centimeters from the center of the useful beam, or
2. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in 41.1(3)"a"(5).

(3) The agency may grant exemptions to 41.1(5)"h"(2) where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the agency shall not permit such exemption.

i. Spot-film exposure reproducibility. Fluoroscopic systems equipped with spot-film (radiographic) mode shall meet the exposure reproducibility requirements of 41.1(6)"d" when operating in the spot-film mode.

j. Radiation therapy simulation systems. Radiation therapy simulation systems shall be exempt from all the requirements of 41.1(5)"a," "c," "d," and "g" provided that:

- (1) Such systems are designed and used in such a manner that no individual other than the patient is in the X-ray room during periods of time when the system is producing X-rays; and

- (2) Systems which do not meet the requirements of 41.1(5)"g" are provided with a means of indicating the cumulative time that an individual patient has been exposed to X-rays. Procedures shall require in such cases that the timer be reset between examinations.

k. Dose-area-product monitor requirements.

- (1) All fluoroscopic equipment installed after July 1, 2002, and used for special procedures (e.g., pacemaker implantation, diagnostic cardiac procedures (catheterization), and therapeutic cardiac procedures (angioplasty-balloon; stent; directional coronary atherectomy; rotational atherectomy; laser atherectomy; radio frequency ablation; and intravascular brachytherapy)) shall be equipped with a dose-area-product monitor capable of recording the total radiation dose received by a patient when the fluoroscopic tube is used. Equipment used and installed prior to July 1, 2002, shall be retrofitted with the radiation exposure device by January 1, 2004.

- (2) Each facility using fluoroscopic equipment for special procedures shall include in the patient's chart and in a log for agency review the patient radiation exposure received per procedure. Adult doses that exceed 300 rad and doses for children (under the age of 18) that exceed 100 rad must be reviewed by the facility's radiation safety committee. The review must document the reason why a dose exceeded 300 rad for adults or 100 rad for children, and the reason must be documented in the committee's minutes. If a facility does not have a radiation safety committee, the facility must provide the agency, within 30 days of the event, documentation stating why the patient's dose exceeded 300 rad for adults or 100 rad for children. Also, if the patient doses noted above are exceeded, the patient's physician must do a follow-up examination of the patient to determine if there is any evidence of dose recorded reaction and to ensure that proper treatment is rendered.

- (3) All fluoroscopic radiation detection devices in this subrule shall be calibrated annually or after repair or replacement.

l. Equipment operation.

- (1) All imaging formed by the use of fluoroscopic X-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

- (2) The use of fluoroscopic X-ray systems by radiologic technologists and students shall be performed under the direct supervision of a licensed practitioner of the healing arts for the purpose of localization to obtain images for diagnostic purposes. The use of fluoroscopic X-ray systems by radiologic assistants shall be as defined in 641—42.6(136C).

- (3) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

(4) Facilities that use fluoroscopic X-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name.

m. Additional requirements for stationary fluoroscopic systems used for cardiac catheterization procedures.

(1) Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the X-ray tube(s). If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 millimeter of lead equivalent.

(2) Protective aprons of not less than 0.25 millimeter of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient). Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant individual must meet the requirements of 641—40.22(136C).

41.1(6) Radiographic systems other than fluoroscopic, dental intraoral, veterinary, or computed tomography X-ray systems.

a. Beam limitation. The useful beam shall be limited to the area of clinical interest. This shall be considered met if a positive beam-limiting device meeting manufacturer's specifications and the requirements of 41.1(6)“h”(2) have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.)

(1) General purpose stationary and mobile X-ray systems and veterinarian systems (other than portable) installed after July 1, 1998.

1. Only X-ray systems provided with means for independent stepless adjustment of at least two dimensions of the X-ray field shall be used.

2. A method shall be provided for visually defining the perimeter of the X-ray field.

- Illuminance shall be greater than 7.5 foot-candles or 80.3 LUX at 100 centimeters or maximum SID whichever is less.

- The total misalignment of the edges of the visually defined field with the respective edges of the X-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the X-ray beam.

3. The agency may grant an exemption on noncertified X-ray systems to 41.1(6)“a”(1)“1” and “2” provided the registrant makes a written application for such exemption and in that application demonstrates it is impractical to comply with 41.1(6)“a”(1)“1” and “2”; and the purpose of 41.1(6)“a”(1)“1” and “2” will be met by other methods.

(2) Additional requirements for stationary general purpose X-ray systems. In addition to the requirements of 41.1(6)“a”(1), stationary general purpose X-ray systems, both certified and noncertified, shall meet the following requirements:

1. A method shall be provided to indicate when the axis of the X-ray beam is perpendicular to the plane of the image receptor, to align the center of the X-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

2. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

3. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in X-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

(3) X-ray systems designed for one image receptor size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(4) Systems designed for or provided with special attachments for mammography. Rescinded IAB 4/8/98, effective 7/1/98.

(5) X-ray systems other than those described in 41.1(6)“a”(1), (2), and (3), and veterinary systems installed prior to July 1, 1998, and all portable veterinary X-ray systems.

1. Means shall be provided to limit the X-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the X-ray beam is perpendicular to the plane of the image receptor.

2. Means shall be provided to align the center of the X-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the X-ray field such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the X-ray beam perpendicular to the plane of the image receptor.

3. 41.1(6)“a”(5)“1” and “2” may be met with a system that meets the requirements for a general purpose X-ray system as specified in 41.1(6)“a”(1) or, when alignment means are also provided, may be met with either:

- An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

- A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. Radiation exposure control devices.

(1) Timers.

1. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

2. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a “zero” or “off” position if either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to “zero.”

(2) X-ray control.

1. Manual exposure control. An X-ray control shall be incorporated into each X-ray system such that an exposure can be terminated by the operator at any time except for exposure of one-half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

2. Each X-ray control shall be located in such a way as to meet the following requirements: Stationary X-ray systems (except podiatry and veterinary units) shall be required to have the X-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure and so that the operator can view the patient while making any exposures; and mobile and portable X-ray systems which are:

- Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of 41.1(6)“b”(2)“2”; or
- Used for greater than one hour and less than one week at the same location, i.e., a room or suite, or in a clinical setting for routine extremities only, or where moving the X-ray system from room to room is impractical, shall meet the requirement of the above paragraph or be provided with a 6.5 foot (1.98 m) high protective barrier which is placed at least 2.7 meters (9 feet) from the tube housing assembly. Written procedures must instruct the operator to remain in the protected area during the entire exposure.

Stationary podiatric systems which do not meet the above requirements shall be provided with a 9-foot exposure button cord which allows the operator to remain behind a protective barrier during the entire exposure. If the protective barrier is moveable, written procedures must be on file at the facility, which dictate that the operator will remain behind the barrier during the entire exposure.